IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

John Barthelow CLASSEN

Application No.: 10/081,705   Group Art Unit: 2161

Filed: 02/21/2002   Examiner: LEROUX, Etienne Pierre

Title: COMPUTER ALGORITHMS AND METHODS FOR PRODUCT SAFETY

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

SUPPLEMENTAL INFORMATION DISCLOSURE

Sir:

Applicant previously filed Information Disclosure Statements on September 23, 2004; November 2, 2004 and July 28, 2005.

Applicant now attaches additional references for the Examiner's review. In addition, the reference identified as Reference Number 4, previously submitted by Applicant in the Supplemental Information Disclosure Statement dated September 23, 2004, is being resubmitted because it was not initialed by the Examiner as being reviewed. Accordingly, the reference is again included in this Supplemental Information Disclosure Statement to ensure the reference has been reviewed by the Examiner.

A check in the amount of $180.00 is enclosed for payment of the necessary fee.

02/03/2006 SHASSEN1 00000070 10081705
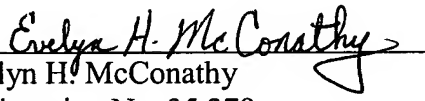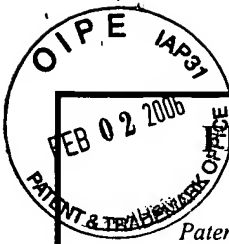01 FC:1806   180.00 OP

CONCLUSION

It is respectfully requested that the information be considered by the Examiner and that a copy of the attached Form PTO-1449 be returned indicating that said references have been considered.

Applicants' undersigned attorney may be reached by telephone at (215) 988-2700. All correspondence should be directed to the below-listed address.

Respectfully submitted,

Dated: January 30, 2006

Evelyn H. McConathy
Registration No. 35,279
DRINKER BIDDLE & REATH LLP
One Logan Square
18th and Cherry Streets
Philadelphia, PA 19103-6996
Tel: (215) 988-3361
Fax: (215) 988-2757

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number

FEE TRANSMITTAL
for FY 2005

Patent fees are subject to annual revision.

Complete if known	
Application Number	10/081,705
Filing Date	02/21/2002
First Named Inventor	CLASSEN
Examiner Name	LEROUX, ETIENNE PIERRE

☒ Applicant claims small entity status. See 37 CFR 1.27

Art Unit	2161

TOTAL AMOUNT OF PAYMENT	($180.00)	Attorney Docket No.	204984[22499-68466]

METHOD OF PAYMENT *(check all that apply)*

☒ Check   ☐ Credit Card   ☐ Money Order   ☐ None   ☐ Other (please identify): _____

- ☐ Deposit Account:
  Deposit Account Number **50-0573**
  Deposit Account Name **Drinker Biddle & Reath LLP**

For the above-identified deposit account, the Director is hereby authorized to: *(check all that apply)*

☒ Charge fee(s) indicated below   ☐ Charge fee(s) indicated below, **except for the filing fee**

☒ Charge any additional fee required under 37 CFR 1.16 and 1.17   ☒ Credit any overpayments

FEE CALCULATION

1. Basic Filing, Search and Examination Fees

Application Type	Filing Fees		Search Fees		Examination Fees		Fees Paid
		Small Entity		Small Entity		Small Entity	
Utility	300	150	500	250	200	100	$500.00
Design	200	100	100	50	130	65	
Plant	200	100	300	150	160	80	
Reissue	300	150	500	250	600	300	
Provisional	200	100	0	0	0	0	

2. Excess Claim Fees

Fee Description		Small Entity
Each claim over 20 or, for Reissues, each claim over 20 and more than in the original patent	50	25
Each independent claim over 3 or, for Reissues, each independent claim more than in the original patent	200	100
Multiple dependent claims	360	180

Total Claims	Extra Claims	Fee	Fee Paid	Multiple Dependent Claims	
				Fee	Fee Paid
* - 20 =	* ×	* =	*		0

Indep. Claims	Extra Claims	Fee	Fee Paid
8 - 3 =	* ×	*	*

3. Application Size Fee

If the specification and drawings exceed 100 sheets of paper, the application size fee due is $250 ($125 for small entity) for each additional 50 sheets or fraction thereof.

Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof	Fee	Fee Paid
*- 100 =	* / 50 =	* (round up to a whole number) ×	125	0

4. Other Fee(s)

	Fees Paid
Non-English Specification, $130 fee (no small entity discount)	
Other: Information Disclosure Statement	180.00

SUBMITTED BY CUSTOMER NO. 23973		Complete (if applicable)	
Name (Print/Type)	EVELYN H. MCCONATHY	Registration No. (Attorney/Agent)	35,279	Telephone	(215) 988.2700
Signature	*Evelyn H. McConathy*			Date	January 30, 2006

Form PTO-1449			DOCKET NO. **204984** [formerly 22499-68466]			APPLN. NO. **10/081,705**	
U.S. Department of Commerce			DOCKET NO. **204984** [formerly 22499-68466]			APPLN. NO. **10/081,705**	
Date Filed: <u>January 30, 2006</u>			APPLICANT: **John Barthelow CLASSEN**				
			FILING DATE: **02/21/2002**			GROUP **2161**	

U.S. PATENT DOCUMENTS

Examiner Initial		Document Number	Date	Name	Class	Subclass	Filing Date if appropriate
	A	5,723,283	03/03/1998	CLASSEN	435	4	
	B	5,728,385	03/17/1998	CLASSEN	424	201.1	
	C	6,219,674	04/17/2001	CLASSEN	707	104	
	D	6,584,472	04/24/2003	CLASSEN	707	104.1	
	E	90/007,638	07/22/2005	CLASSEN			
	F	90/007,639	07/22/2005	CLASSEN			

OTHER DOCUMENT(S) (Including Author, Title, Date, Pertinent Pages, etc.)

	1	*Baker v. Secy of Dept. of Health and Human Servs.*, No. 99-653V, 2003 WL 22416622, (Ct. Fed. Cl. Sept. 26, 2003)
	2	A. Bate, et al., "A Bayesian neural network method for adverse drug reaction signal generation," *Eur J Clin Pharmacol* 54(4) (June 1998) 315-321
	3	C. Baum, et al., "The Spontaneous Reporting System in the United States," *Pharmacoepidemiology*, 2nd ed. New York: John Wiley & Sons, 1994, 125-137
	4	D. Bradbury, "A Bitter Pill to Swallow," *Computing*, 34-35, February 9, 1995
	5	D. Classen et al., "Adverse Drug Events in Hospitalized Patients," 277 *JAMA*, 301-306 (1997)
	6	D. Classen et al., "Computerized Surveillance of Adverse Drug Events in Hospital Patients," 266 *JAMA* 2847-2851 (1991)
	7	D. Classen et al., "Description of a Computerized Adverse Drug Event Monitor Using a Hospital Information System," 27 *Hosp. Pharm.* 774, 776-779, 783 (1992)
	8	D. Classen & S. Pestotnik, "The Computer-Based Patient Record," *Hospital Epidemiology and Infection Control*, 141-154 (2nd Ed., New York: Lippincott Williams & Williams 1999)
	9	R. Evans et al., "A Computer-Assisted Management Program for Antibiotics and Other Antiinfective Agents," 338 *The New England Journal of Medicine*, 232-238 (1998)
	10	R. Evans et al., "Development of Computerized Adverse Drug Event Monitor," *15th Annual Symposium on Computer Applications in Medical Care*, 23-27 (1992)
	11	R. Evans et al., "Evaluation of a Computer-Assisted Antibiotic-Dose Monitor," 33, *Annals. Pharm.*, 1026-1031 (1999)
	12	R. Evans et al., "Preventing Adverse Drug Events in Hospitalized Patients," 28 *Ann. Pharm.* 523-527 (1994)
	13	R. Evans et al., "Prevention of Adverse Drug Events through Computerized Surveillance," *16th Annual Symposium of Computer Applications in Medical Care*, 437-441 (1993)
	14	R. Evans et al., "Using a Hospital Information System to Assess the Effects of Adverse Drug Events," *Seventeenth Annual Symposium on Computer Applications in Medical Care*, 161-165 (1994)
	15	G. Faich, US Adverse Drug Reaction Surveillance 1989-1994, *Pharmacoepidemiology and Drug Safety* 5:393-398 (1996)
	16	Federal Register, vol. 58, no. 105, docket no. 93N-0072 (June 3, 1993)
	17	Finney, D. J. Systematic Signalling of Adverse Reactions to Drugs, *Methods of Information in Medicine*, 13 (1974) 1-10
	18	International Reporting of Adverse Drug Reactions, Final Report of CIOMS Working Group, 1990
	19	Jim Kling, "From hypertension to angina to Viagra," *Modern Drug Discovery* 1(2) (1998), *available at* http://pubs.acs.org/hotartcl/mdd/98/novdec/viagra.htm
	20	M. Lindquist et al., "From Association to Alert–A Revised Approach to International Signal Analysis," *Pharmacoepidemiology and Drug Safety* 8:S15-S25 (April 1999)
	21	David J. Morrow, "New Profits in Old Bottles," *N.Y. Times*, March 19, 1999

Examiner Signature:	Date Considered:

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant(s).

PTO-1449.doc

Form PTO-1449

U.S. Department of Commerce

Date Filed: <u>January 30, 2006</u>

DOCKET NO. **204984** [formerly 22499-68466]	APPLN. NO. **10/081,705**
APPLICANT: **John Barthelow CLASSEN**	
FILING DATE: **02/21/2002**	GROUP **2161**

OTHER DOCUMENT(S) *(Including Author, Title, Date, Pertinent Pages, etc.)*

	22	C.A. Naranjo et al., "A method for estimating the probability of adverse drug reactions," 30 *Clin. Pharmacol. Ther.* (2):239-45 (1981)
	23	V. Pinkston & E. J. Swain, "Management of Adverse Drug Reaction and Adverse Event Data through Collection, Storage and Retrieval," *Detection of New Adverse Drug Reactions*, 281-296 (April 1998) (4th Ed., London: Macmillan Reference Ltd.)
	24	"Post-marketing surveillance for adverse events after vaccination: the national Vaccine Adverse Event Reporting System (VAERS)," MEDWATCH Continuing Education Article (1998)
	25	*Statement of Susan S. Ellenberg before the U.S. House of Representatives, available at* www.fda.gov/ola/1999/anthrax.html (July 21, 1999)
	26	A. Szarfman, "Discussion: A Report on the Activities of the Adverse Events Working Groups: Focus on Improving the Detection of Rare but Serious Events," 1999 Proceedings of the Biopharmaceutical Section, American Statistical Association, Alexandria (VA), *American Statistical Association*, 12-13 (1999) (Szarfman/abstract)
	27	A. Szarfman, "New Methods for Signal Detection," *15th International Conference on Pharmacoepidemiology*, Boston, Mass., August 28, 1999 (Szarfman/ppt)
	28	U.S. Food and Drug Administration, "What Is A Serious Adverse Event?," http://www.fda.gov/medwatch/report/DESK/advevnt.htm
	29	Vaccine Safety Forum, Summaries of Two Workshops, Washington, DC (National Academy Press 1997)

Examiner Signature:	**Date Considered:**

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant(s).

PTO-1449.doc00